

REMARKS

In the Office Action dated February 17, 2010, claims 1-3, 8, 9, 12, 13, 28-31 and 37 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending application Serial No. 10/549,211. Claims 1-3, 8, 9, 12, 28-30, 32-34, 37 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalisty 6,896,007. Claims 13 and 31 were rejected as being unpatentable over Caro in view of Cymbalisty in further view of Healy et al. 5,67,161 (Healy). Claims 35, 36, 39 and 40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro and Cymbalisty in further view of Angelini GB 2298577. For the reasons outlined in detail below, it is respectfully submitted that all of the pending claims are in condition for allowance over the art of record.

Double Patenting

In paragraph 4 of the Office Action, it was noted that certain of the pending claims of the instant application, namely, claims 1-3, 8, 9, 12, 13, 28-31 and 37 were provisionally rejected over claims 1-13 of co-pending application Serial No. 10/549,211. This is only a provisional obviousness-type double patenting rejection because the conflicting claims have not yet been patented. Applicant defers a substantive response to this provisional rejection until such time as the conflicting claims are patented. At that point, if it is called for, a terminal disclaimer will be filed.

Independent Claim 1 and Dependent Claims 2, 8-13, 32 and 34-36

Claims 1, 2, 8, 9, 12, 32 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro in view of Cymbalisty. As to claims 1, 2 and 8, it was asserted in paragraph 7 of the Office Action that Caro discloses the invention substantially as claimed, including a graft capable of use in vivo to carry blood or other bodily fluids comprising a flow tubing having a tubing portion defining a flow lumen, the flow lumen being substantially free of ribs or grooves, wherein the graft is set such that the center line of the flow lumen follows a substantially helical path. It was admitted that Caro does not disclose that the center line of the flow lumen has a helix angle of less than or equal to 45 degrees and the amplitude of the helix is less than or equal to one half of

the internal diameter of the tubing portion, wherein the amplitude of the helical center line divided by the internal diameter of the tubing is at least 5 degrees.

It was asserted that Cymbalistry teaches flow tubing in the analogous art of conduits wherein the tubing is set such that the center line of the flow lumen follows a substantially helical path with a helix angle of 11.3 degrees and an amplitude of the helix less than or equal to one half of the internal diameter of the tubing portion, wherein the amplitude of the helical center line divided by the internal diameter of the tubing is at least 5 % for the purpose of creating dynamic mixing and swirl flow of its contents which prevents the deposition of solids within the tube. It was then asserted that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the generic helical formation of the graft of Caro in view of the specific dimensions taught by Cymbalistry in order to provide flow tubing that creates swirl flow and prevents blockages with the interior of the graft. Finally, it was asserted that the open channel shown in Cymbalistry is also effective to help provide a conduit for blood, even if blockages do form along the tubing walls. This rejection is respectfully traversed.

Claim 1 now recites flow tubing which is for use in vivo to carry blood with the flow tubing being flexible and the flow lumen of a tubing portion having a center line being substantially free of ribs or grooves. A center line of the flow lumen follows a substantially helical path so as to define a helical center line. The helical center line has a helix angle and a helix amplitude, the helix angle being less than or equal to 45 degrees and the helix amplitude being less than or equal to one half of the internal diameter of the tubing portion.

In vascular applications, the flow pulsates or is pulsatile, based on the pumping of the heart. This is discussed in the instant specification where it is stated that the extent to which swirl flow is promoted will vary depending upon the pulsations in blood flow caused by the pumping of the heart. Such pumping changes the Reynolds numbers of arterial blood flow in various regions of the tubing portion (see page 6, line 35 to page 7, line 9). However, in Cymbalistry, the flows appear to be much more continuous. For example, the hydro-mixer B shown in Figure 6 of Cymbalistry carries a slurry which is pumped through the mixer (column 6, lines 55-58), while the hydro-mixer E of Figure 6 carries a stream which presumably flows under gravity (see column 7, lines 30-34 of Cymbalistry. Thus, Cymbalistry merely shows a steady state flow, not a

pulsating flow. In contrast, the claimed invention recognizes the advantages of swirl flow in the context of a pulsating or pulsatile flow which occurs in in vivo grafts. The benefit of such a pulsating flow is that it will flush out stagnant flow regions at lower Reynolds numbers during periods of flow, since then the Reynolds numbers will be higher (see page 7, lines 4-9). This flushing out effect is not recognized or hinted at in Cymbalisty because Cymbalisty is simply not concerned with pulsating flows.

Furthermore, the dynamic velocity vectors for the flows resulting from a pressure pulse are significantly radial in the vascular application. Therefore, they will in fact propel suspended blood particles towards the graft wall. If translated to a pipe carrying a slurry, such as is disclosed by Cymbalisty, this would lead to an increase in abrasion, something which Cymbalisty seeks to avoid.

The failings in Cymbalisty are not cured by Caro. Therefore, it is respectfully submitted that claims 1, 2 and 8 patentably define over Caro even in view of Cymbalisty, or the rest of the cited art. The same is also true of dependent claims 9, 12, 32 and 34.

Claim 13 was rejected over Caro in view of Cymbalisty in further view of Healy. Healy was simply employed for its teaching of a pharmaceutical coating. However, Healy does not provide those teachings which are clearly absent from the asserted combination of Caro and Cymbalisty. Therefore, claim 13 is also in condition for allowance over the asserted three way combination, as well as the remainder of the cited art.

Dependent claims 35 and 36 were rejected as being unpatentable over Caro and Cymbalisty in further view of Angelini. Angelini was said to teach a graft wherein a stent with a large helical angle is used around a graft. However, Angelini also does not provide those teachings which are clearly absent from the asserted combination of Caro and Cymbalisty. As a result, it is respectfully submitted that claims 35 and 36 are also in condition for allowance over the asserted three-way combination, as well as the remainder of the cited art.

Independent Claim 3 and its Dependent Claims 28-31 and 33

Claims 3, 28-30 and 33 were similarly rejected over Caro in view of Cymbalisty. However, claim 3 recites a graft for biomedical use, the graft comprising a flow tubing

which is for use in vivo to carry blood with the flow tubing being flexible. As noted above in connection with claim 1, it is respectfully submitted that the applied combination of Caro and Cymbalisty simply does not teach or disclose the graft recited in claim 3. As such, claim 3 is in condition for allowance over the applied combination of references, as well as the remainder of the cited art. So, too, are dependent claims 28-30 and 33 which merely further patentably define the detailed subject matter of their parent claim.

As to dependent claim 31, this claim was rejected over the three-way combination of Caro, Cymbalisty and Healy. However, Healy does not provide those teachings which are clearly absent from the asserted combination of Caro and Cymbalisty. Therefore, claim 31 is also in condition for allowance over the asserted three-way combination, as well as the remainder of the cited art.

Independent Claim 37 and Dependent Claims 38-40

Independent claim 37 and dependent claim 38 were rejected as being unpatentable over Caro in view of Cymbalisty. Claim 37 recites a graft for in vivo use comprising a flow tubing to carry blood and which tubing is made of biocompatible material, the flow tubing being flexible and including a tubing portion with an internal diameter defining a flow lumen. As noted above in connection with independent claim 1, it is respectfully submitted that the asserted two-way combination of Caro and Cymbalisty does not teach or disclose the subject matter which is recited in claim 37. As such, claim 37 is in condition for allowance over the asserted two-way combination, as well as the remainder of the cited art.

Claims 39 and 40 were rejected over the three-way combination of Caro, Cymbalisty and Angelini. However, as noted above, Angelini does not disclose those teachings which are clearly absent from Cymbalisty and Caro in combination. Therefore, claims 39 and 40 are also in condition for allowance over the asserted three-way combination, as well as the remainder of the cited art.


In view of the foregoing, it is respectfully submitted that all of the pending claims are now in condition for allowance over the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

FAY SHARPE LLP

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Date



Jay F. Moldovanyi
Reg. No. 29,678
1100 Superior Avenue, 7th Floor
Cleveland, Ohio 44114-2579
(216) 861-5582